

REMARKS/ARGUMENTS

Information Disclosure Statement

In the Office Action, the Examiner stated that the Information Disclosure Statement filed by Applicants on December 22, 2000 failed to comply with 37 CFR 1.98(a)(2) because no references were submitted with the form PTO 1449.

Applicants respectfully disagree with the Examiner's refusal to consider the above mentioned IDS. Attached with this Response is a copy of the postcard received from the USPTO showing the official date stamp indicating receipt by the USPTO of the Information Disclosure Statement including the 72 references. Also included as an attachment is the Express Mailing Label showing postage paid of \$39.40 for the package containing the cited references mailed to the USPTO on December 22, 2000. Based on the above-enclosed documents, Applicants believe that the box containing the 72 cited references was received at the USPTO. Replacement copies of the cited non-US patent documents and publications are being sent with this Response per the Examiner's request. Applicants thank the Examiner for retrieving the cited US patents.

Claim Rejections

Original claims 1-11 are of record pending in this application.

Claim Rejection under 35 USC §102(e)

Claims 1 and 5-10 stand rejected under 35 USC 102(e) as being anticipated by Keller (the Keller reference).

It is Applicants belief that the present invention is not anticipated by the Keller reference for several reasons.

The Keller reference does not disclose that the leukoreduction filter is interconnected between the red blood cell collection bag and the red blood cell storage bag, as claimed in Applicants claim 1 and currently amended claim 7.

As taught in the Keller reference on column 85, beginning on line 21, if leukoreduction of the collected red blood cells is deemed appropriate, the red blood cell/storage solution mix “can be” connected to a commercially available red cell/filter bag so that red blood cells are gravity transferred from the collection bag through a filter and into a new storage bag. That a leukoreduction filter “can be connected” does not imply that the filter is preconnected or integrated into the disposable set as claimed in the present invention.

Before this invention, leukoreduction filters were sterile docked manually to both a red blood cell collection bag and a leukoreduced red blood cell storage bag after the collection bag was disconnected from the rest of the disposable set. Having a leukoreduction filter preconnected to a disposable set prevents the additional steps of sterile docking/connecting the leukoreduction filter to the bag containing collected red blood cells to be leukoreduced and the storage bag.

Additionally, having the filter preconnected to the disposable prevents problems with maintaining the sterility of the disposable. Because the filter is preconnected in the disposable, no additional connection steps are required. This lack of connection steps prevent the possibility that the disposable might be contaminated by an operator inadvertently touching the filter or tubing while manually connecting the filter to the red blood cell collection bag and storage bag.

Claim Rejection under 35 USC §103

Claim 2 stands rejected under 35 USC 103(a) as being unpatentable over Keller. Claims 3, 4 and 11 stand rejected as being unpatentable over Keller in view of Minshall.

Applicants disagree with the Examiner’s assessment that “it would have been obvious to connect the air removal bag to the RBC storage bag to remove air therefrom, since it has been held that rearranging parts of an invention involves only routine skill in

the art” As set forth in MPEP 2144.04 VI. C. “The mere fact that a worker in the art could rearrange the parts in the reference device to meet the terms of the claims on appeal is not by itself sufficient to support a finding of obviousness. The prior art must provide a motivation or reason for the worker in the art, without the benefit of the appellant’s specification, to make the necessary changes in the reference device.” Ex parte Chicago Rawhide Mfg. Co. 223 USPQ 351, 353.

There is no teaching or suggestion in the Keller reference which would enable one skilled in the art to interconnect an air removal bag to a red blood cell storage bag as claimed in Applicant’s claim 2. As taught on column 19, beginning on line 23, the vent bag 104 of Keller is interconnected via vent bag tubing assembly 100 to the top of the blood return reservoir 150 of the cassette assembly 100. During use, air is removed which was present since packaging within the cassette assembly.

The blood return reservoir located in the cassette assembly of Keller does not store red blood cells which have been leukoreduced. There is no suggestion in Keller that this reservoir could contain leukoreduced red blood cells. Therefore, it is not a mere rearrangement of parts as the Examiner suggests. It would not be obvious for one skilled in the art to attach an air removal bag to a separate and distinct bag which is used to store leukoreduced red blood cells.

The Examiner attempts to cure the deficiencies of Keller with Minshall (the Minshall reference).

As set forth in MPEP §2243, to establish a *prima facie* case of obviousness, three basic criteria must be satisfied. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art to combine the reference teachings. Second, there must be a reasonable expectation of success. Third, the prior art references must teach or suggest all of the claimed elements. The teaching or suggestion to make the claimed combination and the

reasonable expectation of success must be found in the prior art, not in Applicant's disclosure. See *In re Vaack*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

The Examiner's rejection does not meet the obviousness test set forth above. As previously discussed, the Keller reference does not disclose a preconnected disposable with a leukoreduction filter interconnected to a red blood cell collection bag and a red blood cell storage bag. The Minshall reference does not disclose use of a frangible connector to allow leukoreduced red blood cells to flow into a storage bag. There is no teaching or suggestion in either reference to combine them. Furthermore, if combined, the combination of these references would not produce the invention as claimed by Applicants.

In view of the foregoing remarks, it is believed that the rejections presented in the Office Action of December 2, 2003, have hereby been fully obviated, and can thus be withdrawn. Action to this end is respectfully requested so that claims 1-11 may then be allowed and passed to issue.

It is believed a one month extension fee is due. Please charge this amount to Deposit Account 03-2316.

If there are any questions, or if prosecution can be expedited in any manner by a telephone conference, the Examiner is urged to call the undersigned at the below telephone number.

Respectfully submitted,

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Date

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